DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1467]

DMB

Display Date 12/8/00
Publication Date 12/11/00
Certifier Monnie Oliver

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HbsAg); and Shipment of Blood Products Known Reactive for HBsAg

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Shipment of a Blood Product Prior to Completion of Testing for Hepatitis B Surface Antigen (HBsAg)—(21 CFR 610.40(b)); and Shipment of Blood Products Known Reactive for HBsAg—(21 CFR 610.40(d)) (OMB Control Number 0910–0168)—Extension

Under sections 351 and 361 of the Public Health Service Act (42 U.S.C. 262 and 264), FDA prescribes standards designed to ensure the safety, purity, potency, and effectiveness of biological products including blood and blood components and to prevent the transmission of communicable diseases. To accomplish this, FDA requires, among other things, that each unit of Whole Blood or Source Plasma be tested by a licensed serologic test for hepatitis B surface antigen (HBsAg). Section 610.40(b)(4) (21 CFR 610.40(b)(4)) permits preapproved or emergency shipments of blood products for further manufacturing before the test for HBsAg is completed. To obtain approval for such shipments, the collection facility must submit a description of the control procedures to be used by the collection facility and manufacturer. Proper control procedures are essential to ensure the safe shipment, handling, and quarantine of untested or incompletely tested blood products, communication of test results, and appropriate use or disposal of the blood products based on the test results. Section 610.40(d)(1)(v) and (d)(2)(iv) requires that a collection facility notify FDA of shipments of HBsAg reactive source blood, plasma, or serum for manufacturing into hepatitis B vaccine and licensed or unlicensed in vitro diagnostic biological products, including clinical chemistry control reagents. The reporting requirements inform FDA of the shipment of potentially infectious biological products that may be capable of transmitting disease. FDA's monitoring of such activity is essential should any deviations occur that may require immediate corrective action to protect public safety.

The respondents for this information collection are the blood collection facilities that ship hepatitis B reactive products. Only a few firms are actually engaged in shipping hepatitis B reactive products and making the reports required by § 610.40. Also, there are very few to no emergency shipments per year related to further manufacturing and the only product currently shipped prior to completion of hepatitis B testing is a licensed product, Source Leukocytes. Shipments of Source

Leukocytes are preapproved under the product license applications and do not require notification of shipment. Currently, there have been no respondents reporting emergency or preapproved shipments (§ 610.40(b)). However, FDA is listing one report per year for emergency or preapproved shipments to account for the possibility of future emergency shipments. The estimated number of respondents and total annual responses under § 610.40(d) are based on the annual average of reports submitted to FDA in 1999. The hours per response are based on past FDA experience.

In the **Federal Register** of September 7, 2000 (65 FR 54282), the agency requested comments on the proposed collection of information. No significant comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.40(b)[2]	1	1	0.5	0.5	11
610.40(d)[3]	12	1.83	22	0.5	11.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]The notice involves a brief letter and an enclosure. The letter identifies who is making the shipment, to whom shipped, the nature of the emergency, the kind and quantity shipped, and date of shipment. The enclosure is a copy of the shippers written standard operating procedures for handling, labeling storage, and shipment of contaminated (contagious) product. The burden for development and maintenance of standard operating procedures is approved under OMB Control No. 0910–0116.
[3]The notice of reactive product shipment is limited to information on: The identity of the kind and amount of source material shipped, the name and address of the consignee, the date of shipment, and the manner in which the source material is labeled.

FDA has calculated no additional burden in this information collection package for the labeling requirements in § 610.40(d) because the information and statements on the label necessary for public disclosure and safety are provided by FDA in these regulations. Under 5 CFR 1320.3(c)(2),